

### **REMARKS**

Upon entry of the present amendments, claims 157-219 constitute the pending claims in the present application. Claims 1-156 were previously cancelled. Claims 157-191 stand rejected. Claims 192-219 are new.

#### **Amendments and New Claims**

Applicants have amended claim 157 for clarity. In particular, this claim has been amended to recite "inserting a shaft having a curved portion percutaneously through body tissue in a patient" and "extending the shaft through the patient's vaginal wall subsequent to inserting the shaft through body tissue." Support for this amendment can be found in the specification as originally filed, for example, at least on page 57, last two full paragraphs and Figs. 69-70, which describe and depict the sharpened point 1425 of the shaft being inserted through body tissue of the patient and then extending through the vaginal wall 66 of the patient. Claim 157 is further amended to clarify that the sling assembly end is associated with a sling assembly receiving device. Support for this can be found at least in Figs. 74-75 and the corresponding text, for example page 58, which shows the shaft 2014 of the sling assembly receiving device 2010 associating with the sling assembly via the detachable member 1424.

Applicants have amended claim 158 for clarity, specifically, to recite that "the sling assembly comprises an element for receiving a distal end of a shaft." Support for this amendment can be found in the original specification, for example, at least in Figs. 69-79 and the accompanying text, where it is shown that the sling assembly can be associated with more than one shaft (1414 and 2014).

Applicants have also amended claim 160 for clarity. In particular, to recite that "the sling assembly receiving device comprises a channel for receiving the sling assembly end." Support for this amendment can be found at least in Figs. 74-75 and the corresponding text, for example page 58, which shows the channel of the shaft 2014 of the sling assembly receiving device 2010 receiving the sling assembly via the detachable member 1424. Claim 163 has been similarly amended.

Claim 166 has been amended to correct a typographical error.

Applicants have amended claim 167 for clarity.

Applicants have amended claim 168 to more particularly define the presently claimed method. In particular, this claim has been amended to recite "inserting a first shaft having a curved portion percutaneously through body tissue in a patient; extending the first shaft through the patient's vaginal wall subsequent to inserting the first shaft through body tissue;" and "associating a sling assembly end to an end of a second shaft subsequent to extending the first shaft through the vaginal wall." Support for this amendment can be found in the specification as originally filed, for example, at least on page 58 and in Figs. 72-75, which describe and depict association of the sling assembly via the detachable member 1424 with a second shaft 2014 subsequent to the sharpened point 1425 of the first shaft extending through the vaginal wall 66 of the patient. As a result, Applicants have amended claims 169-170 to correct antecedence.

Applicants have also amended claim 174 to recite "inserting first and second shafts, each having a curved portion, percutaneously through body tissue in a patient so that a distal tip of a shaft extends through the patient's vaginal wall." Support for this amendment can be found in the specification as originally filed, for example, at least on page 57, last two full paragraphs, page 58, fourth whole paragraph, and Figs. 70-71 and 75, which describe and depict the distal tip 1425 of a first shaft in one instance and of a second shaft in another instance extending through the vaginal wall 66 of the patient. Claims 175-176 and 178 have been amended for clarity.

Applicants have also amended claim 182 for clarity. Specifically, as with claims 157 and 168, claim 182 has been amended to clarify that a shaft is inserted through body tissue in a patient and then extended through the patient's vaginal wall subsequent to insertion.

Applicants have amended claim 187 to substantially incorporate subject matter analogous to that of claims 159, 169, and 176.

Applicants have amended claim 188 for clarity.

Claim 190 has been amended to substantially incorporate subject matter analogous to that of claims 166, 173, and 181.

Applicants have amended claim 191 to substantially incorporate subject matter analogous to that of claim 167 and to correct antecedence.

New Claims

Applicants have added new claims 192-219, and support for these can be found in the original specification.

Support for claims 192, 194-197, 201, 203-206, 208-210, 213, and 215-218 can be found at least in the second and third whole paragraphs on page 57.

Support for claims 193, 202, 207, and 214 can be found at least in the fifth and sixth whole paragraphs on page 56.

Claim 198 substantially incorporates subject matter analogous to that of claim 188.

Support for claims 199 and 219 can be found at least in the second whole paragraph on page 55 and the fourth and sixth whole paragraphs on page 56.

Support for claim 200 can be found at least in the second paragraph on page 56.

Support for claims 211-212 can be found at least in Figs. 69-79 and in the corresponding passages in the specification.

The present amendments and newly added claims do not present new matter. Applicants reserve the right to file one or more continuation and/or divisional applications directed to the subject matter of the unamended claims.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Office will be addressed below in the order they appear in the Office Action.

Drawings

The drawings stand objected to under 37 C.F.R. 1.83(a). The Office asserts that the drawings must show every feature of the presently claimed invention specified in the claims, in particular, “the shaft positioned ‘though the vaginal wall’ must be shown...” Applicants respectfully point out that

this feature is depicted in the drawings as originally filed. Notably, Figs. 69-76 and the associated text of the specification depict and describe the sharpened point 1425, which is a shaft and is part of the shaft 1414 and also part of the shaft 2014, extending through the vaginal wall 66. Consequently, the original drawings show the features of the present claims, and corrected or replacement drawings are not necessary. Applicants request reconsideration and withdrawal of the objection.

Priority

Applicants note that their claim for priority under 35 U.S.C. 119(e) or 35 U.S.C. 120, 121, or 365(c) has been acknowledged. Nevertheless the Office asserts that the priority documents of the present application (U.S. Patent Application Nos. 10/015,114 and 09/023,965 and U.S. Provisional Patent Application No. 60/038,171) fail to provide adequate support or enablement under 35 U.S.C. 112 for one or more of the present claims. Specifically, the Office finds that the priority documents do not provide enablement for a method wherein a shaft is “percutaneously inserted and through the vaginal wall or associating a sling assembly to the shaft extending through the vaginal wall.”

Applicants respectfully disagree, and as noted above, refer the Office to pages 57-58 and Figs. 69-76, which describe and depict the shaft 1414 being inserted percutaneously through and extending through the vaginal wall 66, for example, via the sharpened point 1425, which is also a shaft. Moreover, the above passages and figures also describe and depict the sling assembly (comprising at least the sling 1418) associated with the shaft 1414 and the shaft 2014. The Office also mentions a feature of “associating a sling assembly to the shaft extending through the vaginal wall.” Without addressing the merits of this aspect of the objection, Applicants submit that it is rendered moot by the present amendments.

Hence, the subject matter claimed by the instant application is present in the above priority applications, and as a result this application properly claims priority to those priority applications.

Claim Rejections – 35 U.S.C. 112 – Claims 157-191

Claims 157-191 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office asserts that the specification does not disclose the subject matter of a “method including inserting a shaft

percutaneously through the vaginal wall or associating a sling assembly to the shaft extending through the vaginal wall.” For the reasons noted above in discussing priority, Applicants assert that the presently claimed subject matter is supported by the original specification and the present written description rejection is rendered moot. Applicants request reconsideration and withdrawal of the rejection.

*Claim Rejections – 35 U.S.C. 102(b) – Claims 157-164, 167-171, 174-179, 182-188 over Kammerer*

Claims 157-164, 167-171, 174-179, 182-188 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Published Patent Application No. 2002-0188169 to Kammerer et al. (“Kammerer”). Without addressing the merits of this rejection, Applicants note that the earliest priority date that could be ascribed to the subject matter of Kammerer cited in the outstanding Office Action is June 9, 1999, the filing date of U.S. Provisional Patent Application No. 60/138,231, assuming that the subject matter relied on by the Office is disclosed in this provisional application. Yet, the present application claims priority as far back as February 13, 1997, the filing date of U.S. Provisional Patent Application No. 60/038,171, and certainly at least as far back as February 13, 1998, the filing date of U.S. Patent Application No. 09/023,965 (now U.S. Patent No. 6,423,080), which has an identical specification as the present application. As noted above, the present claims are fully supported by the originally filed priority applications and are thus entitled to the claimed priority dates. Since such dates predate the earliest possible priority date of Kammerer, this reference does not qualify as prior art for supporting a rejection under 35 U.S.C. 102(b). Accordingly, Applicants request reconsideration and withdrawal of the rejection.

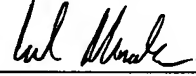
**CONCLUSION**

In view of the above arguments and amendments, Applicants believe the pending application is in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000.

Should an extension of time beyond that mentioned above be required, Applicants hereby petition for same and request that the additional extension fee and any other fee required for timely consideration of this submission be charged to Deposit Account No. 18-1945, under Order No. MIY-P04-006 from which the undersigned is authorized to draw.

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Respectfully submitted,

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